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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,992	06/09/2005	Hiroshi Matsui	081356-0243	1370

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MARTIN, PAUL C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/537,992	MATSUI, HIROSHI	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/09/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-12 are pending in this application and were examined on their merits.

Claim Objections

Claim 12 is objected to because of the following informalities: The word "surfactant" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the claims and disclosure what is meant by "different measurement conditions", for example does this apply to pH, temperature, reaction components, etc.?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Sugiuchi (6,794,157 B1).

Sugiuchi teaches a method for measuring cholesterol in low density lipoprotein (LDL) and total cholesterol in a biological sample, whereby cholesterol in LDL and total cholesterol in a biological sample are quantified with a single measurement (Column 12, Lines 5-60 and Column 13, Lines 54-66 and Column 14, Lines 1-54).

Sugiuchi teaches a method wherein the first step comprises reacting cholesterol in lipoproteins other than LDL in a biological sample, and a second step in which cholesterol in the remaining LDL is reacted (Column 12, Lines 5-60).

Sugiuchi teaches a method wherein a measurement value reflecting the existing amount of cholesterol in lipoproteins other than the LDL in a biological sample and a measurement value reflecting the existing amount of cholesterol in the LDL are obtained with a single measurement and then the existing amounts of cholesterol in the LDL and total cholesterol in the biological sample are simultaneously measured based on the two previous values (Column 12, Lines 5-60 and Column 13, Lines 54-66 and Column 14, Lines 1-54).

Sugiuchi teaches a method wherein in the presence of a surfactant acting on lipoproteins other than LDL, the first step comprises causing cholesterol esterase and cholesterol oxidase to act on lipoproteins other than the LDL in a biological sample, converting the generated hydrogen peroxide into a quinine dye and then measuring the generated NADH (Column 12, Lines 5-60 and Column 9, Lines 21-57).

Sugiuchi teaches a method wherein the second step comprises adding a surfactant acting at least on the LDL to the reaction product of the first step, causing cholesterol esterase and cholesterol oxidase to act on the remaining LDL and then measuring generated NADH (Column 12, Lines 5-60 and Column 9, Lines 47-57).

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Sugiuchi teaches a method wherein cholesterol in LDL in blood is quantified by finding the difference between absorbances obtained as measurement values in the first and second steps (Column 12, Lines 55-59).

Sugiuchi teaches a method wherein total cholesterol is quantified by finding total absorbance based on a change in absorbance obtained as a measurement value in the first step and a change in absorbance as a measurement value in the second step (Column 14, Lines 39-43).

Sugiuchi teaches a reagent composition for simultaneously measuring cholesterol in LDL and total cholesterol in a biological sample (Column 13, Lines 54-66 and Column 14, Lines 1-44).

Sugiuchi teaches a reagent composition which comprises a surfactant acting on lipoproteins other than LDL, a surfactant acting on at least LDL, cholesterol esterase, and cholesterol oxidase (Column 13, Lines 15-51).

Sugiuchi teaches a reagent composition which comprises the surfactant acting on lipoproteins other than LDL, the surfactant acting on at least LDL, cholesterol esterase, and cholesterol oxidase (Column 13, Lines 15-51).

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It is deemed inherent in the method of Sugiuchi that a method yielding the concentrations of HDL and LDL in a biological sample would necessarily then be able to provide one with the total cholesterol value based on the addition of the two values.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiuchi (6,794,157 B1).

The teachings of Sugiuchi were discussed above.

Sugiuchi does not teach a method in which analysis is carried out under different measurement conditions with a single measurement using an automated analyzer for clinical and chemical examination.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the method of Sugiuchi for determining LDL and total cholesterol in a biological sample with an automated analyzer method for clinical and chemical examination because this would serve to make the process more efficient and timely, desired characteristics in testing processes used in clinical settings. The ordinary artisan would have been motivated to apply the automated analyzer to the method of Sugiuchi in order to conduct the process in a more high-throughput fashion. The ordinary artisan would have had a reasonable expectation of success because of the prevalence and familiarity that the ordinary artisan would have had with automated analyzation methods and apparatus.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

02/28/06

PATRICIA LEITH
PRIMARY EXAMINER
